

Exhibit A

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The Declaration of Allulose and Calories from Allulose on Nutrition and Supplement Facts Labels: Guidance for Industry

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Office of Nutrition and Food Labeling
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740
(Tel)240-402-1450
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**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition**

October 2020

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The Declaration of Allulose and Calories from Allulose on Nutrition and Supplement Facts Labels: Guidance for Industry¹

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

This guidance provides our current view on the declaration of allulose on Nutrition and Supplement Facts labels, as well as on the caloric content of allulose. This guidance also advises manufacturers of our intent to exercise enforcement discretion for the exclusion of allulose from the amount of “Total Sugars” and “Added Sugars” declared on the label and the use of a general factor of 0.4 calories per gram (kcal/g)² for allulose when determining “Calories” on the Nutrition and Supplement Facts labels pending review of the issues in a rulemaking.

In arriving at our decision to consider the exercise of enforcement discretion, we considered data and information provided in citizen petitions and in comments to the draft guidance, and other information submitted to us. We received a citizen petition requesting the exemption of allulose from the declaration of “Total Carbohydrate,” “Total Sugars,” and “Added Sugars” on the Nutrition Facts label (Docket Number FDA-2015-P-1201) (Ref. 1). We also considered a citizen petition requesting the use of a general factor for caloric value of allulose of 0.4 calories per gram (kcal/g) (Docket Number FDA-2016-P-2030) (Ref. 3), and another citizen petition requesting the use of a general factor for the caloric value of allulose of 0.2 kcal/g (Docket

¹ This guidance has been prepared by the Office of Nutrition and Food Labeling in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

² Calories per gram or kilocalories per gram (kcal/g) has been defined as the amount of heat energy needed to raise the temperature of a kilogram of water 1°C (determined at 14.5°C to 15.5°C) and is the unit that has been traditionally used for expressing the energy value of foods (Ref. 2).

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Number FDA-2017-P-1463) (Ref. 4). We considered these citizen petitions (as well as comments submitted to the dockets for these citizen petitions) in conjunction with comments to a proposed rule titled “Food Labeling: Revision of the Nutrition and Supplement Facts Labels” (79 FR 11880, March 3, 2014) (“the proposed rule”). We also conducted an independent review of the scientific evidence related to the cariogenic potential, metabolism, and caloric value of, and glycemic response to, allulose.

FDA’s guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

II. Background

Allulose or D-psicose (D-ribo-2-hexulose) is a monosaccharide with a molecular formula of $C_6H_{12}O_6$, and is an epimer of D-fructose. D-psicose occurs naturally and is present in small amounts in wheat, fruits (e.g., raisins, dried figs) and in many other foods (e.g. molasses, maple syrup, and brown sugar). It can also be synthesized from fructose by enzymatic epimerization which converts fructose to D-psicose. FDA has not objected to three Generally Recognized as Safe (GRAS) notifications regarding the use of this substance as a sugar substitute in certain conventional foods and beverages (GRAS Notification Number (GRN) 400 (Ref. 5), GRN 498 (Ref. 6), and GRN 693 (Ref. 7)).

On April 10, 2015, we received a citizen petition from Tate & Lyle Ingredients America LLC (Tate & Lyle) (Docket Number FDA-2015-P-1201) (Ref. 1) requesting that we amend 21 CFR 101.9 to exempt allulose from being included as a carbohydrate, sugar,³ or added sugar on the Nutrition Facts label for foods and beverages. The citizen petition provided data and other information suggesting that allulose is different from other sugars in that it is not metabolized by the human body, has negligible calories (0.2 kcal/g or less), and does not contribute to increases in blood glucose or insulin levels.⁴

The citizen petition was submitted after the comment period closed for the proposed rule. The proposed rule did not specifically address allulose; however, in a supplemental proposed rule (80 FR 44303, July 27, 2015), we proposed (among other things) to establish a Daily Reference Value (DRV) of 10 percent of total energy intake from added sugars and to require the declaration of the percent Daily Value (DV) for added sugars on the label.

³ The petition was submitted at a time when the Nutrition Facts label used the term “Sugars.” On May 27, 2016, FDA issued a final rule to amend the Nutrition Facts and Supplement Facts label regulations. The final rule, among other things, replaced the term “Sugars” with “Total Sugars.” See 81 FR 33742 and 21 CFR 101.9(c)(6)(ii) (requiring declaration of “Total Sugars” on the Nutrition Facts label). Therefore, in this guidance, we refer to “Total Sugars.”

⁴ The petition did not include data or other information on the association between consumption of allulose and dental caries.

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While neither the proposed rule nor the supplemental proposed rule addressed the labeling of allulose, we received comments on allulose (81 FR 33742 at 33795-96). According to the comments, allulose is approximately 70 percent as sweet as sucrose and contributes less than 0.2 kcal/g to the diet. The comments stated that allulose is added to foods and beverages as a partial replacement for sugars or high-fructose corn syrup because of its low, near zero, calorie content and other organoleptic properties (e.g., mouthfeel, texture, etc.). One comment said we should not include allulose in the declaration for “Total Carbohydrate” and “Added Sugars” because of the properties mentioned above. In contrast, another comment said we should include allulose in the declaration of “Total Carbohydrate” for nutrition labeling purposes, but not in the declaration of “Total Sugars” or “Added Sugars” because allulose does not have the metabolic properties of fructose or other sugars and does not contribute calories or raise blood sugar levels like other sugars. The comments said that, upon ingestion, approximately 70 percent of allulose is absorbed in the small intestine, passes into the bloodstream and is then excreted intact in the urine, without significant metabolism; the other 30 percent, which is not absorbed in the small intestine, is transported to the large intestine where it is not fermented and is then excreted intact.

On May 27, 2016, we issued a final rule titled “Food Labeling: Revision of the Nutrition and Supplement Facts Labels” (81 FR 33742) (“final rule”). In the final rule, we stated that we needed additional time to fully consider the information provided in the citizen petition and the comments we received to the proposed rule (81 FR 33742 at 33796). Therefore, we did not reach a decision as to whether allulose should be excluded from the declaration of “Total Carbohydrate,” “Total Sugars,” and/or “Added Sugars.” We stated that allulose, as a monosaccharide, must be included in the amount of the declaration of “Total Carbohydrate,” “Total Sugars,” and “Added Sugars” pending any future rulemaking that would otherwise consider excluding allulose from the declaration.

After we issued the final rule, we received two citizen petitions regarding allulose. One citizen petition, submitted by the Food Lawyers (Docket Number FDA-2016-P-2030) (Ref. 3), requested, among other things, that we amend 21 CFR 101.9(c)(1)(i) by adding the following:

“(G) Using the following general factor for caloric value of Allulose (also known as D-Allulose, D-psicose): Allulose — 0.4 calories per gram.”

The citizen petition included information to support the caloric value of 0.4 kcal/g for allulose.

Another citizen petition, submitted by Tate & Lyle (Docket Number FDA-2017-P-1463) (Ref. 4), requested, among other things, that we amend 21 CFR 101.9(c)(1)(i) to include the following in a new section (G):

“(G) Using the following general factor for caloric value of Allulose (also known as, D-allulose, D-psicose): Allulose – 0.2 calories per gram.”

The petition included information to support the caloric value of 0.2 kcal/g for allulose.

In a comment to the Tate & Lyle citizen petition, the Food Lawyers stated that they fully supported a caloric value for allulose of 0.2 kcal/g.

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On August 13, 2018, Tate & Lyle submitted the results from a clinical trial that assessed the impact of allulose on dental plaque pH. On August 22, 2018, Matsutani Chemical Industry Co. LTD submitted the results of a clinical trial that assessed the impact of allulose consumption on dental plaque pH as well as a copy of U.S. Patent No. 8,496,915, including an *in vitro* study that examined the final medium pH and the growth of a bacterial strain that causes dental caries when cultured with allulose.⁵ We considered these studies in our review of the scientific evidence related to the cariogenic potential of allulose (Ref. 8).

In the *Federal Register* of April 18, 2019 (84 FR 16272), we announced the availability of a draft guidance titled “The Declaration of Allulose and Calories from Allulose on Nutrition and Supplement Facts Labels: Guidance for Industry,” in which we announced our tentative views on the declaration of allulose on Nutrition and Supplement Facts labels and caloric content of allulose. The draft guidance also advised manufacturers of our intent to exercise enforcement discretion for the exclusion of allulose from the amount of “Total Sugars” and “Added Sugars” declared on the label, and for use of a general factor of 0.4 kcal/g for allulose when determining “Calories” on the Nutrition and Supplement Facts labels pending review of the issues in a rulemaking. We have considered comments to the draft guidance, and we have made modifications, where appropriate, that are reflected in this final guidance. We also conducted an independent review of the scientific evidence on the cariogenic potential, metabolism, and caloric value of, and glycemic response to, allulose (Ref. 8).

III. Declaration of Allulose on the Nutrition and Supplement Facts Labels

1. FDA’s Consideration of the Caloric Value of Allulose

We did not determine a specific caloric value for allulose in the final rule. Therefore, under 21 CFR 101.9(c)(1)(B), a caloric value of 4 kcal/g must currently be used for allulose because it is a carbohydrate. The citizen petitions from the Food Lawyers (Ref. 3) and from Tate & Lyle (Ref. 4) identified two human studies on the metabolism of allulose. Our search of the literature did not reveal any additional human studies that determined a caloric value of allulose. We provide a summary of the studies in our memorandum to the file (Ref. 8).

The two citizen petitions (Refs. 4 and 3) provided data supporting the use of 0.2 kcal/g for allulose and 0.4 kcal/g for allulose.⁶ Based on our review of the evidence (Ref. 8), we conclude that the caloric contribution of allulose is very low (i.e., no more than 0.4 kcal/g) because the majority of allulose is excreted intact in the urine, and because allulose is poorly fermented in the gut. We have limited evidence from human studies, using different methodologies, upon which to determine the caloric value of allulose. Therefore, we intend to exercise enforcement discretion for the use of a caloric value of 0.4 kcal/g for allulose because, based on the range of data we have, such a caloric value would not underestimate the caloric contribution. We intend

⁵ Both the Tate & Lyle and Matsutani Chemical Industry submissions were in support of the 2015 Tate & Lyle citizen petition. The submissions can be found in docket FDA-2015-P-1201.

⁶ One petitioner subsequently supported a caloric value of 0.2 kcal/g rather than 0.4 kcal/g.

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to exercise enforcement discretion with respect to the use of a caloric value of 0.4 kcal/g when calculating declarations on Nutrition and Supplement Facts labels pending rulemaking to consider amending 21 CFR 101.9(c)(1)(i) regarding the use of a general factor for the caloric value of allulose.

2. FDA's Consideration of Allulose as a Carbohydrate

Total Carbohydrate content is determined for the purposes of nutrition labeling by subtraction of the sum of the crude protein, total fat, moisture, and ash from the total weight of the food (21 CFR 101.9(c)(6)). The calculation method is described in A.L. Merrill and B.K. Watt, "Energy Value of Foods--Basis and Derivation" (Ref. 2). "Carbohydrate" as a class captures a variety of substances ranging from mono and disaccharides to numerous types of non-digestible carbohydrates, some of which are dietary fibers. As previously mentioned, allulose is a monosaccharide. It has the chemical composition of a carbohydrate and is captured under the method for determination of Total Carbohydrate in 21 CFR 101.9(c)(6).

The 2015 Tate & Lyle citizen petition (Ref. 1) suggested that allulose should not be included in the Total Carbohydrate definition because, in part, it does not raise blood glucose levels, and thus could be confusing for individuals who are interested in monitoring their blood glucose levels, such as diabetics. We have traditionally based our decision on labeling of carbohydrates on whether a substance is chemically a carbohydrate (79 FR 11880 at 11900). As we explained in the final rule, we had invited comment on and considered:

whether carbohydrates should be classified and declared in nutrition labeling based on their chemical definition (which is the current method) or on their physiological effect (e.g., attenuation of blood sugar or laxation), and whether additional types of carbohydrates (e.g., starch) should be listed separately on the Nutrition Facts label. We explained that carbohydrates include starch, sugars, sugar alcohols, and dietary fibers and that different carbohydrates have different physiological effects [79 FR 11879 at 11901]. Within the different types of carbohydrate (i.e., starch, sugars, sugar alcohols, and dietary fibers), too, specific carbohydrates may have different physiological effects (e.g., different types of dietary fibers) making it difficult to apply a definition that is based on physiological effects across a category of carbohydrates. Furthermore, analytical methods for measuring different types of carbohydrates are based on chemical structure rather than physiological effect. Given the various components of total carbohydrate and different types of physiological effects of each, we decided not to change our provisions for the classification or declaration of carbohydrates specified in 21 CFR 101.9(c)(6).

81 FR 33742 at 33795.

In summary, we considered whether a physiological effect-based definition was appropriate for total carbohydrates and determined that it was not because of the wide variety of effects of different types of carbohydrates.

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Furthermore, as discussed in the final rule, the information in the Nutrition Facts label is not targeted to individuals with acute or chronic disease (e.g., diabetes, chronic kidney disease, or cardiovascular disease). The nutrient declaration and percent Daily Values on the label are to help consumers make more informed choices to consume a healthy diet and not intended for the clinical management of an existing disease (81 FR 33742 at 33750). Inclusion of allulose in the declaration of “Total Carbohydrate” on Nutrition and Supplement Facts label is also consistent with how we have considered the declaration of other substances that are captured under the method that is currently used for the determination of “Total Carbohydrate” on the label, including those that provide few or no calories, such as sugar alcohols and dietary fibers.

Therefore, because allulose is a carbohydrate, it is captured under the calculation method for “Total Carbohydrate” described in 21 CFR 101.9(c)(6), like a number of other substances without significant caloric contribution. We have determined that our existing definition of carbohydrate is the most appropriate and allulose must be included in the amount of “Total Carbohydrate” declared on the label under the existing regulations.

3. FDA’s Consideration of Allulose as a Sugar

Total Sugars are defined in 21 CFR 101.9(c)(6)(ii) as the sum of all free mono- and disaccharides (such as glucose, fructose, lactose, and sucrose). Allulose is a monosaccharide that is an epimer of D-fructose. In the final rule, we said that consumption of sugars continues to be associated with an increased risk of dental caries; thus, the “Total Sugars” declaration continues to be necessary to assist consumers in maintaining healthy dietary practices (81 FR 33742 at 33798).

The 2015 Tate & Lyle citizen petition (Ref. 1) suggested that allulose should not be included in the “Total Sugars” declaration because it is not metabolized like a sugar, does not raise blood glucose levels, and inclusion in the “Total Sugars” declaration would be confusing to consumers, particularly those who monitor their blood glucose levels. A summary of the evidence related to the cariogenic potential, metabolism, and caloric value of, and glycemic response to, allulose is provided in a memorandum to the file (Ref. 8).

We have traditionally determined what is captured under the “Total Sugars” declaration on the label by chemical structure. Due to advances in food technology, novel sugars are now available that are not metabolized and that do not contribute 4 kcal/g to the diet like other traditional sugars. Consequently, we need to consider how information about sugars like allulose should be captured on the label.

Our current thinking is that, consistent with the goal of section 403(q) of the Federal Food, Drug, and Cosmetic Act for the nutrient declarations to assist consumers in maintaining healthy dietary practices, we should consider not only the chemical structure of sugars, but also other evidence, including their association with dental caries and how they are metabolized in the body (e.g., caloric contribution and their effect on blood glucose and insulin levels), when determining whether a sugar should be included in the declaration of “Total Sugars” on the label.

Sugars are known to be associated with an increased risk of dental caries (21 CFR 101.80). Sugars that are metabolized by oral bacteria produce polymers that adhere to the tooth surface

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(i.e., dental plaque) and generate acids resulting in a decrease in the pH (Ref. 9) of dental plaque. The low pH provides an environment that allows for decalcification of the teeth (e.g., solubilization of calcium from dental enamel), increasing the risk of dental caries (or tooth decay) (Ref. 10). The “Total Sugars” declaration provides consumers with information that they can use to evaluate the contribution of sugars in their diet to the risk of dental caries. We therefore believe that evidence related to the association between consumption of a sugar and dental caries is an important consideration when determining whether the amount of a particular sugar in a serving of a product should be excluded from the “Total Sugars” declaration on the label.

Mono and disaccharides typically provide 4 kcal/g (Ref. 2). If a consumer wishes to determine how many calories are contributed by sugars in their diet, they can multiply the grams of Total Sugars per serving by 4 kcal/g. Current dietary recommendations suggest that Americans should limit their consumption of calories from sugars, and particularly added sugars, and stay within calorie limits (Ref. 11). As a result, manufacturers are substituting sugars that provide much less than 4 kcal/g, such as allulose, for sugars that provide 4 kcal/g in an effort to reduce caloric content. Including sugars that contribute much less than 4 kcal/g to the diet in the “Total Sugars” declaration would not accurately reflect the caloric contribution to the diet of sugars like allulose that contain much less than 4 kcal/g. Therefore, we consider the caloric contribution of a sugar to be an important consideration when determining if the sugar should be excluded from the amount of the “Total Sugars” declaration.

During digestion, disaccharides are hydrolyzed into two monosaccharide units in the upper small intestine. Primarily, the body breaks sugars down into glucose, which is used as energy by cells in the body or stored as glycogen (Ref. 12). Consuming sugar increases circulating glucose in the blood stream. The presence of glucose in the blood triggers the release of the hormone insulin from the pancreas. Insulin stimulates the uptake of glucose by muscle and adipose tissue. Therefore, when traditional sugars like glucose, fructose, lactose, and sucrose are consumed, there is a rise in blood glucose and insulin levels (Ref. 12). The “Total Sugars” declaration provides consumers with information that they can use to determine whether a product contains sugars that are likely to cause an increase in circulating blood glucose and insulin levels. Some consumers expect that when they eat sugars, the result will be an increase in blood glucose and insulin levels. Therefore, we consider a sugar’s effect on blood glucose and insulin levels to be important considerations when determining whether a sugar should be excluded from the “Total Sugars” declaration.

Allulose, like other non-cariogenic carbohydrate sweeteners listed in 21 CFR 101.80(c)(2)(ii), does not result in a decrease in dental plaque pH below 5.7, which is associated with decalcification of the dental enamel (Ref. 10). Therefore, given the low cariogenic potential of allulose, we conclude that allulose does not promote dental caries. Furthermore, based on our review of the evidence, we conclude that allulose, once ingested, is rapidly absorbed (within 1 hour) and cleared from plasma in 24 hours, and 70% of orally consumed allulose is eliminated

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intact in urine and feces within 48 hours (Ref. 8).⁷ Allulose produces only a negligible increase in glycemic and insulinemic responses and is not readily fermented in the large intestine, providing no more than 0.4 kcal/g (Ref. 8). Based on the totality of the available evidence from which scientific conclusions can be drawn, allulose does not promote dental caries and is virtually unmetabolized in the human body (Ref. 8).

As previously discussed, allulose does not result in a decrease in the dental plaque pH below 5.7, at which decalcification of dental enamel may begin, and thus, does not promote dental caries. It provides much less than 4 kcal/g. Additionally, the consumption of allulose produces only a negligible increase in glycemic and insulinemic responses. Therefore, we intend to exercise enforcement discretion with respect to the exclusion of allulose from the amount of “Total Sugars” declared on the label pending future rulemaking regarding amending the definition of “Total Sugars.”

Finally, we note that allulose must be declared in the ingredient statement in accordance with 21 CFR 101.4 if it is present in a product so that consumers can determine when it is an ingredient in a food.

4. FDA’s Consideration of Allulose as an Added Sugar

Added sugars are sugars that are either added during the processing of foods, or are packaged as such, and include sugars (free, mono- and disaccharides), sugars from syrups and honey, and sugars from concentrated fruit or vegetable juices that are in excess of what would be expected from the same volume of 100 percent fruit or vegetable juice of the same type.

As previously discussed, we did not decide whether allulose should be excluded from the amount of “Added Sugars” declared on the label in the final rule and stated that allulose must be included in the declaration of “Added Sugars” pending any future rulemaking regarding excluding allulose from the declaration.

A summary of the evidence related to the metabolism of allulose is provided in our memorandum to the file (Ref. 8). Based on our review of the scientific evidence, we conclude that allulose is virtually unmetabolized in the human body. Based on this, as well as the evidence regarding caloric value and dental caries, as previously discussed, we intend to exercise enforcement discretion if allulose is not included in the amount of “Total Sugars” declared on the label. The “Added Sugars” declaration is a subset of the “Total Sugars” declaration. Applying similar logic, through the exercise of our enforcement discretion, we consider that allulose should not be included in the “Added Sugars” declaration, including the %DV declaration. Furthermore, we note that, based on information about usage levels provided in GRAS notices (Refs. 5-7), we expect that the caloric contribution of allulose will be insignificant in most cases and will substantially reduce the amount of total calories and calories from added sugars in products where it replaces those added sugars.

⁷ In this mass-balance study, 70.4% of the ¹⁴C radiotracer orally administered to seven subjects was eliminated as intact allulose in urine and feces, while 1.5 % was identified as glucose and fructose, 11.7% were not identified (unknown), and the remaining radioactivity was lost during the process (Ref. 8).

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Therefore, we intend to exercise enforcement discretion with respect to the exclusion of allulose from the gram amount of and the %DV for “Added Sugars” declared on Nutrition and Supplement Facts labels, pending future rulemaking.

We again note that allulose must be declared in the ingredient statement in accordance with § 101.4 if it is present in a product so that consumers can determine when it is an ingredient in a food.

IV. Paperwork Reduction Act of 1995

This guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required.

However, this guidance refers to previously approved FDA collections of information. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 101 have been approved under OMB control number 0910-0381.

V. References

The following references marked with an asterisk (*) are on display in the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday. They also are available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. Citizen Petition Submitted by Tate & Lyle Ingredients Americas LLC requesting that Allulose be Exempt From Being Included As a Carbohydrate, Sugar, or Added Sugar in the Nutrition Facts Label on Foods and Beverages, April 10, 2015. Docket Number FDA-2015-P-1201.*
2. Merrill AL and Watt BK. “Energy value of foods...basis and derivation,” Human Nutrition Research Branch, Agricultural Research Service, U.S. Department of Agriculture, Agriculture Handbook No. 74, 1973.*
3. Citizen Petition Submitted by The Food Lawyers Requesting the Use of a General Factor of 0.4 Calories Per Gram of Allulose on the Nutrition Facts Label, July 12, 2016. Docket Number FDA-2016-P-2030.*

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4. Citizen Petition Submitted by Tate & Lyle Ingredients Americas LLC Requesting the Use of a General Factor for Caloric Value of Allulose of 0.2 kcal/g, March 8, 2017. Docket Number FDA-2017-P-1463.*
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<https://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=400> (accessed September 16, 2020).*
6. FDA GRAS Notification No. 498.
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8. U.S. Food and Drug Administration Memorandum to the File: Scientific Review of the Evidence on the Cariogenic Potential, Metabolism, and Caloric Value of, and Glycemic Response to, Allulose, 2019.*
9. Newman H.N. "The Relation between Plaque and Dental Caries." J R Soc Med. 1986;79 Suppl 14:1-5.
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12. Gropper, S.S., Smith, J.L., Groff, J.L. (2009). *Advanced Nutrition and Human Metabolism* (5th ed.), Chapter 3: Carbohydrates. Belmont, CA: Wadsworth, Cengage Learning.